Citation:

He K, Hu FB, Colditz GA, Manson JE, Willett WC, Liu S. Changes in intake of fruits and vegetables in relation to risk of obesity and weight gain among middle-aged women. *Int J Obes Relat Metab Disord.* 2004 Dec; 28(12): 1,569-1,574.

PubMed ID: 15467774

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the direct relation between intake of fruits and vegetables and risk of obesity and long-term weight gain among middle-aged women.

Inclusion Criteria:

- Participants of the Nurses' Health Study: 121,700 female registered nurses aged 30 to 55 years from 11 US states
- 1984 was considered as the baseline since the food-frequency questionnaire (FFQ) was expanded in that year.

Exclusion Criteria:

- At baseline (the year 1984), women were excluded if they had a history of cardiovascular disease, cancer or diabetes
- Also excluded were participants who provided incomplete information or implausible information.

Description of Study Protocol:

Recruitment

- Participants of the Nurses' Health Study: 121,700 female registered nurses aged 30 to 55 years from 11 US states
- 1984 was considered as the baseline since the FFQ was expanded in that year.

Design

Prospective cohort study with 12-year follow up conducted in the Nurses' Health Study.

Dietary Intake/Dietary Assessment Methodology

Using a semi-quantitative FFQ, participants were asked to report the frequencies of 16 fruit items and 28 vegetable items consumed during the previous year. For each fruit or vegetable, a standard unit or portion size was specified. Nine responses were possible, ranging from "never" to "six or more times per day." The response to each food item was converted to average daily intake.

Statistical Analysis

- Changes in intake of fruits and vegetables were ranked from the largest decrease to the largest increase during the follow-up period and used quintiles of this variable in the analyses. Multivariate ORs were examined by controlling for baseline covariates rather than changes in covariate status
- The median values of quintiles of changes in fruit and vegetable intake were used as a continuous variable for the tests for linear trend. To estimate the mean difference of changes in body weight or BMI from 1984 to 1996 by category of fruit and vegetable intake, general linear models with least-square means were used
- Data were stratified according to whether participants' baselines BMIs were greater or less than 25kg/m^2 or whether they had incident chronic diseases.

Data Collection Summary:

Timing of Measurements

Baseline at 1984 with 12-year follow-up.

Dependent Variables

Risk of obesity and weight gain.

Independent Variables

Changes in intake of fruits and vegetables.

Description of Actual Data Sample:

- *Initial N:* 121, 700 female registered nurses
- *Attrition (final N):* 74,063
- *Age:* 38 to 63 years
- *Other relevant demographics:* 11 US states.

Summary of Results:

Odds Ratios (95% CI) of Obesity or Major Weight Gain According to Changes in Fruit and Vegetable Intake from 1984 to 1994

	Quintiles of Changes in Intake	

	Q1	Q2	Q3	Q4	Q5	P for Trend
Fruits and vegetables						
Median change	-2.36	-0.49	0.64	1.83	3.99	
Obesity						
Model 1	1.00	0.84 (0.78 to 0.91)	0.86 (0.79 to 0.93)	0.79 (0.73 to 0.86)	0.79 (0.73 to 0.86)	<0.0001
Model 2	1.00	0.86 (0.77 to 0.95)	0.87 (0.78 to 0.96)	0.81 (0.72 to 0.90)	0.76 (0.69 to 0.86)	<0.0001
Major weight gain						
Model 1	1.00	0.71 (0.56 to 0.89)	0.70 (0.56 to 0.88)	0.62 (0.49 to 0.79)	0.72 (0.57 to 0.91)	0.002
Model 2	1.00	0.80 (0.62 to 1.03)	0.82 (0.63 to 1.05)	0.73 (0.56 to 0.95)	0.72 (0.55 to 0.93)	0.01

Author Conclusion:

Increasing intake of fruits and vegetables may reduce long-term risk of obesity and weight gain among middle-aged women.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	N/A

4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes

7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes